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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,539	01/11/2002	Thomas R. Cech	015389-002630US	4930

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EXAMINER	
LIETO, LOUIS D	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,539	CECH ET AL.	
	Examiner	Art Unit	
	Louis D Lieto	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-38 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the parent application 08/854,050, upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 6-36 of this application.

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). Claims 6-36 are to specific cell types that are not disclosed in the parent application 08/854,050. The instant application is a direct continuation of application 08/912,951, as such claims 6-36 are given the effective filing date of August 14, 1997. Claims 1-5, 37 and 38 are deemed to be adequately supported by the parent application 08/724,643 and are granted benefits of the earlier effective filing date, October 1, 1996.

If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent

application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application. Applicant needs to update the dates and status of the parent applications. Specifically application 08/912,951, which was issued as U.S., patent 6,475,789, and application 08/854,050 that was issued as U.S. patent 6,261,836. Appropriate correction is required.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37

CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for full length human telomerase reverse transcriptase protein, does not reasonably provide enablement for fragments and variants there of as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant has described the polynucleotide sequence of SEQ ID NO:1 and presented TRT motifs. However the claims as written encompass all fragments and subsequences, and contain no defining functional limitations. Without limitations defining the functions of such fragments and subsequences, one of skill in the art would not know how they could be used and thus would also not know ho to make them. The amino acid sequence of a polypeptide determines its structural and functional properties, and prediction of function is complex and

well outside the realm of routine experimentation, because accurate prediction of a fragment's structure from mere sequence data is limited. Since information regarding the structural and functional requirements of the claimed fragments is lacking, it is unpredictable as to which fragments, if any, are usable. Further, while recombinant techniques are available, it is not routine in the art to screen large number of fragments where the expectation of obtaining any function is unpredictable. Thus one of skill in the art would require additional guidance, such as information regarding the expected function of the claimed fragments. Without such guidance, not present in the instant specification, it would require undue experimentation by one of skill in the art to practice the invention as claimed.

The phrase embryonic stem (ES) cells has a distinct meaning in the art. Thomson et al. teaches that the defining characteristics of the ES cell is, (i) derivation from the preimplantation or periimplantation embryo, (ii) prolonged undifferentiated proliferation, and (iii) stable development potential to form derivatives of all three embryonic germ layers {Thomson et al. (1998) Science, Vol. 282, page 1145, paragraph 1}. John Gearhart, in a review of Thomson et al. article, explains that Thomson's report of five human ES cell lines possessing the characteristics outlined above represents a major technical achievement, since prior to the Thomson et al. publication, it was not a foregone conclusion that ES cells could be derived from human embryos {Gearhart et al. (1998) Science, Vol. 282, 1061-1062, bridging paragraph}. Furthermore, Campbell et al. teaches that, in species other than the mouse the isolation of ES cells has proved more difficult. There are reports of ES-like cell lines in a number of species. However, as yet there are no reports of any cell lines, which contribute to the germ line in any species other than the mouse {Campbell et al. (1997) Theriogenology, Vol. 47 (1), page 65, paragraph 2}. Thus,

based on the art recognized unpredictability of isolating and using embryonic stem cells or other totipotent embryonic cells from mammals, and in view of the lack of guidance provided by the specification for identifying and isolating embryonic cells which can contribute to the germ line of a human the skilled artisan would not have had a reasonable expectation of success in generating any and all totipotent cells, embyronic stem cells, or embryonic germ cells according to the instant invention.

Further, at the time of filing a skilled practitioner in the art would not have been able to use human embryonic stem cells or germ cells to diagnosis or treat human diseases. The specification does not indicate which diseases or class(es) of disease would be treated with the hTRT recombinant human embryonic stem cells or germ cells. In addition to the complexity of isolating and culturing human ES cells the skilled artisan cannot envision how to generate hTRT recombinant human embryonic stem cells or germ cells. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 refers to a polynucleotide that hybridizes under stringent conditions to a polynucleotide complimentary to the sequence of SEQ ID NO:1. Claims 2-38 depend on Claim 1. The term "stringent hybridization conditions" is vague and indefinite. Stringent hybridization

conditions could include a wide variety of salt concentrations, annealing temperatures and/or the presence of other alternatives. It is not clear from the body of the claim what constitutes a "stringent condition". As a result, the metes and bounds cannot be determined.

Double Patenting

Claims 1-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,475,789. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Claim 1 of U. S. Patent No. 6,475,789 is a species of the broader genus of the claims in the instant application. Specifically claim 1, of the instant application, is to a polynucleotide that hybridizes to a sequence complementary to SEQ ID NO:1 under stringent conditions, which broadly encompasses Claim 1 of U. S. Patent No. 6,475,789 that asserts a polynucleotide that hybridizes to a sequence complementary to SEQ ID NO:1 at 5° C to 25°C below T_m in aqueous solution at 1M NaCL. It is well established that a species of a claimed invention renders the genus obvious. In re Schaumann , 572 F.2d 312, 197 USPQ 5 (CCPA 1978).

In the instant application claim 2 depends on claim 1so as to limit it to human cells. Claim 6 of U. S. Patent No. 6,475,789 provides the same limitation to human cells. Claim 2, in the instant application, is rejected since it encompasses the invention of U. S. Patent No. 6,475,789.

Claims 3-5, in the instant application, are rejected since they are species within the genus of invention of U. S. Patent No. 6,475,789. The patented claims are broader in that they do not place any limitations on the polynucleotides encoding hTRT, while the instant claims recite additional elements. However, the limitation of claim 3 in the instant application is described in

U. S. Patent No. 6,475,789 (paragraph 130, 233 and 503). Claims 4 and 5, in the instant application, are to a polynucleotide comprising a constitutive promoter and an inducible promoter, respectively. U. S. Patent No. 6,475,789 describes a polynucleotide operably linked to a promoter (paragraph 28,29,35,48,50 and Fig 9). One of skill in the art will appreciate that all promoters are either constitutive or inducible, a fact well known at the time of application. Thus the limitations of claims 3-5, in the instant application, are encompassed by the invention of U. S. Patent No. 6,475,789.

Claims 6-32, in the instant application each limit claim 1 to a single human cell type. Claim 1 of U. S. Patent No. 6,475,789 recites a mammalian cell, which encompasses all human cell types. However, the cells recited in claims 6-36, in the instant application, are described in Table 3 of U. S. Patent No. 6,475,789 as human cells in which hTRT expression may be increased. Therefore, the patented claim renders the instant claim obvious.

Claims 33-36, in the instant application each limit claim 1 to a single human stem cell or stem cell type. Claim 7 of U. S. Patent No. 6,475,789 recites a human stem cell, which encompasses all human stem cell types. Further, the patent clearly teaches the use of human stem cell types, see Table 3 of U. S. Patent No. 6,475,789. Therefore, the patented claim renders the instant claim obvious.

Claim 37, in the instant application, is to a human cell, wherein the polynucleotide encodes a full-length, naturally occurring human telomerase reverse transcriptase. Claim 2 of U. S. Patent No. 6,475,789 recites a mammalian cell, wherein the recombinant polynucleotide encodes a full-length naturally occurring human telomerase reverse transcriptase, which encompasses human cells. However, the patent clearly teaches the preferred use of human cells,

see Table 3 of U. S. Patent No. 6,475,789. Therefore, the patented claim renders the instant claim obvious.

Claim 38, in the instant application, comprises a polynucleotide that encodes a human telomerase reverse transcriptase having the amino acid sequence of SEQ ID NO:2. Claim 1 of U. S. Patent No. 6,475,789 recites a recombinant polynucleotide comprising a nucleic acid sequence that encodes a telomerase reverse transcriptase protein, variant, or fragment. The specification of U. S. Patent No. 6,475,789 teaches SEQ ID NO: 2 as an encoded telomerase reverse transcriptase protein. Therefore, the patented claim renders the instant claim obvious.

Claims 1-38 are free of the art.

No claims allowed

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy J Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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